

Express Mail Label No. EL209599009US  
U.S. National Phase Entry of PCT/GB00/01118  
"Polycationic Carbohydrates as Immunostimulants in Vaccines"  
Filed: 20 September 2001  
PRELIMINARY AMENDMENT

Version with markings to show changes made

4. (Amended) A pharmaceutical composition comprising a biologically active agent which is capable of generating a protective immune response in an animal, and a polycationic carbohydrate according to [any one of] claim[s] 1 [to 3].

6. (Amended) A pharmaceutical composition according to claim 5 which comprises particles comprising

(i) a biologically active agent which is able to produce an immune response in an animal to which it is administered;

(ii) a first material capable of forming particles; and

(iii) a polycationic carbohydrate according to [any one of] claim[s] 1 [to 3].

10. (Amended) A composition according to claim 9 wherein the chitin derivative is chitosan, chitosan chloride, or chitosan glutamate or a polycationic carbohydrate according to claim 2 [or claim 3].

11. (Amended) A composition according to [any one of] claim[s] 6 [to 10] wherein the particle comprises microspheres, microparticles or liposomes.

13. (Amended) A composition according to [any one of] claim[s] 6 [to 12]  
wherein the first material is a polymeric material which has a molecular weight of 100kDa or  
more.

14. (Amended) A composition according to [any one of] claim[s] 6 [to 13]  
wherein the first material comprises poly-(L-lactide).

15. (Amended) A composition according to [any one of] claim[s] 6 [to 14]  
wherein the ratio of the first material to the polycationic carbohydrate is from 99:1 to 9:1  
w/w.

16. (Amended) A composition according to [any one of] claim[s] 6 [to 15]  
wherein the biologically active agent is capable of generating a protective immune response  
against tetanus, diptheria, or *Yersinia pestis*.

18. (Amended) A composition according to [any one of] claim[s] 6 [to 17]  
which is adapted for intranasal application.

19. (Amended) A composition according to [any one of] claim[s] 6 [to 17]  
which is adapted for parenteral administration.

20. (Amended) A composition according to [any one of] claim[s] 6 [to 19]

which further comprises a chemical compound selected from

- (A) a polyamino acid,
- (B) a vitamin or vitamin derivative,
- (C) cationic pluronics,
- (D) a clathrate,
- (E) a complexing agent,
- (F) cetrimides[:]<sub>2</sub>,
- (G) an S-layer protein; or
- (H) methyl-glucamine.

23. (Amended) A method for producing a pharmaceutical composition, which method comprises encapsulating a biologically active agent in a first material, in the presence of a polycationic carbohydrate according to [any one of] claim[s] 1 [to 3].

30. (Amended) A method of protecting an animal against a pathogen, said method comprising administering to said animal, a protective agent which is able to stimulate the animal's immune system to produce a response which is protective against said pathogen, and an immunostimulant comprising a polycationic carbohydrate according to [any one of] claim[s] 1 [to 3].

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31. (Amended) A method of protecting an animal against a pathogen, said method comprising administering to said animal, a protective agent which is able to stimulate the animal's immune system to produce a response which is protective against said pathogen, in the form of a composition according to [any one of] claim[s] 6 [to 22].

32. (Amended) A method according to claim 30 [or claim 31] wherein the protective agent which is able to stimulate the animal's immune system to produce a response which is protective against said pathogen, and an immunostimulant comprising a polycationic carbohydrate is applied parenterally or to a mucosal surface.

35. (Amended) The use of a polycationic carbohydrate or a pharmaceutically acceptable derivative thereof according to [any one of] claim[s] 1 [to 3] as an immunostimulant, in the preparation of a vaccine for use in prophylactic or therapeutic treatment.